

CONFIDENTIAL
EXHIBIT J

CONFIDENTIAL INFORMATION – SUBJECT TO PROTECTIVE ORDER

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

SUN PHARMACEUTICAL INDUSTRIES)	
LTD. and RANBAXY SIGNATURE, LLC,)	
)	
Plaintiffs,)	
)	
v.)	
)	C.A. No. 1:18-cv-648 (VAC)(MPT)
SAPTALIS PHARMACEUTICALS, LLC,)	
)	
Defendant.)	
)	
)	

**PLAINTIFFS’ OBJECTIONS AND RESPONSES TO
DEFENDANT’S FIRST SET OF INTERROGATORIES TO PLAINTIFFS (NOS. 1-9)**

Pursuant to Rules 26 and 33 of the Federal Rules of Civil Procedure and the Local Rules of Civil Practice and Procedure for the District of Delaware, Plaintiffs Sun Pharmaceutical Industries Ltd. and Ranbaxy Signature, LLC (together, “Plaintiffs”) hereby object and respond to Defendant Saptalis Pharmaceuticals, LLC’s (“Saptalis”) First Set of Interrogatories (Nos. 1–9) (the “Interrogatories”), served on July 26, 2018, as follows:

PRELIMINARY STATEMENT

Plaintiffs have not yet completed their investigation of the facts related to this case, nor have they completed discovery or preparation for trial. The following responses are based solely upon the information presently available to Plaintiffs. It is anticipated that further discovery, independent investigation, legal research, and analysis may supply additional facts and establish entirely new factual conclusions and legal contentions, all of which may lead to the discovery of additional information, thereby resulting in additions to, changes in, and variations from these responses pursuant to Federal Rule of Civil Procedure 26(e).

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OBJECTIONS TO DEFINITIONS AND INSTRUCTIONS

Plaintiffs object to these Interrogatories, including the Definitions and Instructions applicable thereto, to the extent set forth below. The following objections shall be applicable to, and shall be included in, Plaintiffs' response to each Interrogatory, whether or not mentioned expressly in any particular response. Plaintiffs do not waive these objections by also stating specific objections to any particular Interrogatory.

1. Plaintiffs incorporate by reference the Objections to Definitions and Instructions set forth in Plaintiffs' Responses and Objections to Plaintiffs' First Set of Production of Documents and Things (Nos. 1–34).

2. Plaintiffs object to each Interrogatory to the extent that it calls for legal conclusions or seeks litigation strategy. Plaintiffs' responses herein are to matters of fact only, and should not be construed as stating or implying any conclusions of law.

3. Plaintiffs object to each Interrogatory to the extent that it prematurely seeks expert discovery or testimony.

4. Plaintiffs object to each Interrogatory to the extent that it prematurely seeks to limit and define Plaintiffs' claims and contentions in this litigation before discovery is completed, and further, to the extent that it prematurely seeks information to be disclosed prior to the date set by the Court in the Scheduling Order for completion of discovery.

5. Plaintiffs object to each Interrogatory to the extent it includes multiple subparts, each of which constitute a separate Interrogatory, and shall construe each such separate Interrogatory as a single interrogatory for the purpose of paragraph 3.c. of the Scheduling Order entered in this litigation.

6. Plaintiffs object to the definition of "identify" in Instruction F as overly broad and

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unduly burdensome to the extent that it seeks to impose obligations on Plaintiffs that exceed or are otherwise inconsistent with Plaintiffs' obligations under the Federal Rules of Civil Procedure, the Local Rules of the Court, the Default Standard for Discovery, or any other applicable law or rule. To the extent that Plaintiffs agree to identify a person, entity, document, communication, or thing, Plaintiffs will provide reasonable information allowing the same to be identified.

7. Plaintiffs object to the Interrogatories, and the Definitions and Instructions therein, to the extent that Saptalis seeks information concerning "each," "any," or "all" persons, communications, documents, or things, on the grounds that such Interrogatories are unreasonable, overly broad, and unduly burdensome. Any response by Plaintiffs to any such Interrogatory is not an admission that Plaintiffs have agreed to produce all responsive documents and things without limitation, but rather that Plaintiffs have agreed to produce responsive and non-privileged documents and things, if any, that can be located after a reasonable search. When appropriate, Plaintiffs may provide summary information of representative documents and things.

8. The objections and responses provided herein are subject to, and are stated without waiver of Plaintiffs' right to make additional and supplemental objections to the Interrogatories, and to revise, correct, amend, supplement, or modify these objections and responses upon the discovery of additional facts and materials, further investigation, and other developments in the litigation.

9. Plaintiffs reserve their right to raise all questions of authenticity, relevance, materiality, privilege, and admissibility of any and all documents and things produced in response to the Interrogatories, for any purpose that may arise in this litigation, and further to object to the use of those documents and things on any basis.

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10. Plaintiffs reserve the right to object to further discovery into the subject matter of any Interrogatory and to the introduction of any of the information produced in response to any Interrogatory.

**SPECIFIC OBJECTIONS AND RESPONSES TO
SAPTALIS'S FIRST SET OF INTERROGATORIES (NOS. 1-9)**

INTERROGATORY NO. 1: Identify the ingredients and amounts of each ingredient in Defendant's metformin formulations described in the documents Defendant provided to Plaintiffs or their counsel from Defendant's ANDA No. 211309, that Plaintiffs or their counsel reasonably believed, at the time the Complaint in this action was filed, may literally infringe the claimed element "a polyhydroxy alcohol present in an amount of about 15 to about 55% by weight" in claim 1 of the '957 patent.

OBJECTIONS: Plaintiffs object to this Interrogatory as prematurely seeking expert discovery and testimony. Plaintiffs further object to this Interrogatory as prematurely seeking information that will be provided pursuant to the Court's Default Standard for Discovery. Plaintiffs also object to this Request to the extent that it seeks information protected by attorney-client privilege, work-product immunity, joint defense privilege, common interest privilege, and/or any other applicable privilege, protection or immunity.

RESPONSE: Subject to and without waiver of the foregoing and referenced objections, Plaintiffs respond that they will provide information responsive to this Interrogatory in their initial claim chart relating the accused product described in Saptalis's ANDA to the asserted claims of the Patent-in-Suit that the product infringes, which will be produced pursuant to Paragraph 4(b) of the Court's Default Standard for Discovery and the Scheduling Order entered in this litigation. Plaintiffs further respond that they will provide information responsive to this Interrogatory through expert discovery. Moreover, Plaintiffs respond that they will produce relevant and non-privileged documents and things from which the information requested in this Interrogatory can be ascertained pursuant to Rule 33(d) of the Federal Rules of Civil Procedure, to the extent that

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they exist, are within the possession, custody, or control of Plaintiffs, and are located after a reasonable search, at an appropriate time pursuant to the Federal Rules of Civil Procedure, the Local Rules of Civil Practice, and by order of the Court. Plaintiffs reserve the right to revise, clarify, and/or supplement this Interrogatory response in accordance with the Federal Rules of Civil Procedure.

INTERROGATORY NO. 2: Identify the ingredients and amounts of each ingredient in Defendant's metformin formulations described in the documents Defendant provided to Plaintiffs or their counsel from Defendant's ANDA No. 211309, that Plaintiffs or their counsel reasonably believed, at the time the Complaint in this action was filed, may infringe under the doctrine of equivalents the claimed element "a polyhydroxy alcohol present in an amount of about 15 to about 55% by weight" in claim 1 of the '957 patent, explain the factual bases for such reasonable belief of infringement under the doctrine of equivalents, and identify all documents consulted or relevant to such belief.

OBJECTIONS: Plaintiffs object to this Interrogatory as prematurely seeking expert discovery and testimony. Plaintiffs further object to this Interrogatory as prematurely seeking information that will be provided pursuant to the Court's Default Standard for Discovery. Plaintiffs also object to this Request to the extent that it seeks information protected by attorney-client privilege, work-product immunity, joint defense privilege, common interest privilege, and/or any other applicable privilege, protection or immunity.

RESPONSE: Subject to and without waiver of the foregoing and referenced objections, Plaintiffs respond that they will provide information responsive to this Interrogatory in their initial claim chart relating the accused product described in Saptalis's ANDA to the asserted claims of the Patent-in-Suit that the product infringes, which will be produced pursuant to Paragraph 4(b) of the Court's Default Standard for Discovery and the Scheduling Order entered in this litigation. Plaintiffs further respond that they will provide information responsive to this Interrogatory through expert discovery. Moreover, Plaintiffs respond that they will produce relevant and non-privileged documents and things from which the information requested in this Interrogatory can

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be ascertained pursuant to Rule 33(d) of the Federal Rules of Civil Procedure, to the extent that they exist, are within the possession, custody, or control of Plaintiffs, and are located after a reasonable search, at an appropriate time pursuant to the Federal Rules of Civil Procedure, the Local Rules of Civil Practice, and by order of the Court. Plaintiffs reserve the right to revise, clarify, and/or supplement this Interrogatory response in accordance with the Federal Rules of Civil Procedure.

INTERROGATORY NO. 3: State the expiration date of the '957 patent, explain the bases of that expiration date, and identify all documents providing the bases of that determination.

OBJECTIONS: Plaintiffs object to this Request to the extent that it seeks information protected by attorney-client privilege, work-product immunity, joint defense privilege, common interest privilege, and/or any other applicable privilege, protection or immunity. Plaintiffs further object to this Request as overbroad, unduly burdensome, and not proportional to the needs of this case to the extent that it seeks production of “all” documents, when the relevant information can be supplied by the production of fewer than “all” such documents.

RESPONSE: Subject to and without waiver of the foregoing and referenced objections, Plaintiffs respond that expiration date of the '957 patent listed in the FDA's Orange Book is September 14, 2023. Plaintiffs' investigation into this question is ongoing, and Plaintiffs reserve the right to revise, clarify, and/or supplement this Interrogatory response in accordance with the Federal Rules of Civil Procedure.

INTERROGATORY NO. 4: Identify all patents and patent applications related to the Patent-In-Suit, including but not limited to all continuations, divisionals, continuations-in-part, and foreign counterparts, all persons involved in the decision(s) to file any such counterpart applications, all persons who participated (*e.g.*, provided technical input, reviewed or commented on communications from the United States Patent and Trademark Office (“USPTO”), prepared and/or filed papers with the USPTO, participated in interviews with the examiners, provided invention disclosures and/or technical information) in the preparation and/or prosecution of the Patent-In-Suit, the applications from which the Patent-In-Suit issued, any foreign counterpart applications to the Patent-In-Suit, and state how these individuals were involved.

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OBJECTIONS: Plaintiffs object this Interrogatory as overly broad, unduly burdensome, and seeking information that is not relevant to any claim or defense in this litigation to the extent that it seeks the identity of “all” persons “involved in the decision(s)” to file any counterpart applications, the identity of “all persons ... who participated” in communications with the USPTO, “prepared and/or filed” papers with the USPTO, “participated in interviews” with USPTO examiners, and provided information concerning “the preparation and/or prosecution of the Patent-in-Suit, the applications from which the Patent-In-Suit issued, any foreign counterpart applications to the Patent-In-Suit,” and further to the extent that it seeks information concerning how such persons “were involved.” Plaintiffs further object to the terms “participated” and “involved” as vague and ambiguous. Additionally, Plaintiffs object to this Request to the extent that it seeks information protected by attorney-client privilege, work-product immunity, joint defense privilege, common interest privilege, and/or any other applicable privilege, protection or immunity.

RESPONSE: Subject to and without waiver of the foregoing and referenced objections, Plaintiffs respond that the '957 patent issued from U.S. Application No. 10/382,442 (the “'442 application”). The '442 application is a continuation of U.S. Application No. 09/923,491 (the “'491 application”), which issued as U.S. Patent No. 6,559,187. The '491 application claims priority from Provisional Application No. 60/223,391. Plaintiffs further respond that International Publication No. WO 02/11716, which issued from International Application No. PCT/IB01/01409, is a foreign counterpart of the '957 patent. Plaintiffs further respond that they will produce relevant and non-privileged documents and things from which information requested in this Interrogatory can be ascertained pursuant to Rule 33(d) of the Federal Rules of Civil Procedure, to the extent that they exist, are within the possession, custody, or control of Plaintiffs, and are located after a

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reasonable search, at an appropriate time pursuant to the Federal Rules of Civil Procedure, the Local Rules of Civil Practice, and by order of the Court. Plaintiffs reserve the right to revise, clarify, and/or supplement this Interrogatory response in accordance with the Federal Rules of Civil Procedure.

INTERROGATORY NO. 5: State with specificity all facts pertaining to the first sale, first offer for sale, first description in a printed publication anywhere in the world, first disclosure to any individual, corporation or other entity outside Plaintiffs except for the USPTO, and first public use in the United States, of the alleged invention(s) claimed in the Patent-In-Suit, including, without limitation, the date upon which the claimed alleged invention was first offered for sale; the location of the offer; identification of the offeree; identification of the offeror; the date the claimed alleged invention(s) was first described in a printed publication anywhere in the world; the name and publisher of the publication in which the claimed alleged invention(s) was first described; the date upon which the claimed alleged invention(s) was first publicly used in the United States; and the location in which the claimed alleged invention(s) was first publicly used in the United States.

OBJECTIONS: Plaintiffs object to this Interrogatory as overly broad, unduly burdensome, and seeking that is not relevant to any claim or defense in this litigation or proportional to the needs of this case, to the extent that it seeks: the identity of “all facts” pertaining to the first sale concerning the inventions claimed in the Patent-in-Suit; to “the location” and “identification” of any offeree and/or offeror; “all facts” pertaining to any “printed publication anywhere in the world;” the “name and publisher” of any such publication; and “the location in which [the inventions claimed in the Patent-in-Suit were] first publicly used in the United States.” Plaintiffs further object to the terms “first disclosure” and “first described” as vague and ambiguous. Additionally, Plaintiffs object to this Interrogatory to the extent that it calls for legal conclusions. Moreover, Plaintiffs object to this Interrogatory to the extent that it includes multiple subparts, each of which constitutes a separate Interrogatory. Plaintiffs further object to this Request to the extent that it seeks information protected by attorney-client privilege, work-product immunity, joint defense privilege, common interest privilege, and/or any other applicable

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privilege, protection or immunity.

RESPONSE: Subject to and without waiver of the foregoing and referenced objections, Plaintiffs respond that Riomet® (metformin hydrochloride oral solution, 500 mg/5 mL) was approved on September 11, 2003, as an adjunct to diet and exercise to improve glycemic control in adults and children with type 2 diabetes mellitus. The application that led to the '957 patent was filed on March 6, 2003, and a portion thereof was published on August 7, 2003. Plaintiffs further respond that they will produce relevant and non-privileged documents and things from which information requested in this Interrogatory can be ascertained pursuant to Rule 33(d) of the Federal Rules of Civil Procedure, to the extent that they exist, are within the possession, custody, or control of Plaintiffs, and are located after a reasonable search, at an appropriate time pursuant to the Federal Rules of Civil Procedure, the Local Rules of Civil Practice, and by order of the Court. Plaintiffs reserve the right to revise, clarify, and/or supplement this Interrogatory response in accordance with the Federal Rules of Civil Procedure.

INTERROGATORY NO. 6: Identify all prior art to the '957 patent known to Plaintiffs, including, but not limited to, any patents, publications, public disclosures, or products relating to a liquid pharmaceutical composition containing metformin, and for each prior art identified, provide the date upon which Plaintiffs first became aware of any such prior art, the circumstances upon which Plaintiffs first became aware of any such prior art, and the identity of all persons employed by or affiliated with Plaintiffs (or their corporate predecessors) known or believed by you to have knowledge of such prior art.

OBJECTIONS: Plaintiffs object to this Interrogatory as overly broad, unduly burdensome, and seeking information that is not relevant to any claim or defense in this litigation or is not proportional to the needs of this case, to the extent that it seeks information concerning “all persons employed by or affiliated with Plaintiffs ... known or believed ... to have knowledge of” prior art related to the '957 patent. Plaintiffs further object to this Interrogatory to the extent that it prematurely seeks expert discovery and testimony. Additionally, Plaintiffs object to this

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Interrogatory to the extent that it seeks legal conclusions regarding what constitutes prior art. Plaintiffs further object to this Request to the extent that it seeks information protected by attorney-client privilege, work-product immunity, joint defense privilege, common interest privilege, and/or any other applicable privilege, protection or immunity.

RESPONSE: Subject to and without waiver of the foregoing and referenced objections, Plaintiffs respond that they will produce the certified file history of the Patent-in-Suit, in accordance with paragraph 4(a) of the Court's Default Standard for Discovery and the Scheduling Order entered in this litigation, which identifies the prior art considered by the USPTO during the prosecution of the Patent-in-Suit. Such prior art includes U.S. Patent Nos. 3,174,901; 3,174,921; 4,379,785; 4,572,912; 4,639,436; 4,904,769; 5,594,016; 5,614,492; and 6,031,004. Such prior art also includes foreign patent documents WO/99/55320; WO 02/11716; EP 0 177 303; and EP 0 373 103. Plaintiffs further respond that they will produce relevant and non-privileged documents and things from which information requested in this Interrogatory can be ascertained pursuant to Rule 33(d) of the Federal Rules of Civil Procedure, to the extent that they exist, are within the possession, custody, or control of Plaintiffs, and are located after a reasonable search, at an appropriate time pursuant to the Federal Rules of Civil Procedure, the Local Rules of Civil Practice, and by order of the Court. Plaintiffs reserve the right to revise, clarify, and/or supplement this Interrogatory response in accordance with the Federal Rules of Civil Procedure.

INTERROGATORY NO. 7: Identify all documents that relate to any publication, including but not limited to any document disclosed or distributed to any person or entity not employed by Plaintiffs at the time of the disclosure, prior to August 7, 2001, disclosing a liquid pharmaceutical composition containing metformin, and explain the circumstances of such publication, disclosure and distribution, including the date(s) and location(s) of such disclosure, the persons who made the disclosure and the recipients of such disclosure.

OBJECTIONS: Plaintiffs object to this Interrogatory to the extent that it prematurely seeks expert discovery and testimony. Additionally, Plaintiffs object to this Interrogatory to the

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extent that it seeks legal conclusions. Plaintiffs further object to this Request to the extent that it seeks information protected by attorney-client privilege, work-product immunity, joint defense privilege, common interest privilege, and/or any other applicable privilege, protection or immunity. Moreover, Plaintiffs object to this Interrogatory to the extent that it seeks documents or things that are not within Plaintiffs' possession, custody, or control.

RESPONSE: Subject to and without waiver of the foregoing and referenced objections, Plaintiffs respond that they will produce relevant and non-privileged documents and things from which information requested in this Interrogatory can be ascertained pursuant to Rule 33(d) of the Federal Rules of Civil Procedure, to the extent that they exist, are within the possession, custody, or control of Plaintiffs, and are located after a reasonable search, at an appropriate time pursuant to the Federal Rules of Civil Procedure, the Local Rules of Civil Practice, and by order of the Court. Plaintiffs reserve the right to revise, clarify, and/or supplement this Interrogatory response in accordance with the Federal Rules of Civil Procedure.

INTERROGATORY NO. 8: Identify all documents and things relating to the distribution of any liquid pharmaceutical composition containing metformin to any person not employed by Plaintiffs at the time of the distribution, prior to August 7, 2001, and explain the circumstances of such distribution, including the date(s) and location(s) of such distribution, the persons who made the distribution and the recipients of such distribution.

OBJECTIONS: Plaintiffs object to this Interrogatory to the extent that it prematurely seeks expert discovery and testimony. Additionally, Plaintiffs object to this Interrogatory to the extent that it seeks legal conclusions. Plaintiffs further object to this Request to the extent that it seeks information protected by attorney-client privilege, work-product immunity, joint defense privilege, common interest privilege, and/or any other applicable privilege, protection or immunity. Moreover, Plaintiffs object to this Interrogatory to the extent that it seeks documents or things that are not within Plaintiffs' possession, custody, or control.

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RESPONSE: Subject to and without waiver of the foregoing and referenced objections, Plaintiffs respond that they will produce relevant and non-privileged documents and things from which information requested in this Interrogatory can be ascertained pursuant to Rule 33(d) of the Federal Rules of Civil Procedure, to the extent that they exist, are within the possession, custody, or control of Plaintiffs, and are located after a reasonable search, at an appropriate time pursuant to the Federal Rules of Civil Procedure, the Local Rules of Civil Practice, and by order of the Court. Plaintiffs reserve the right to revise, clarify, and/or supplement this Interrogatory response in accordance with the Federal Rules of Civil Procedure.

INTERROGATORY NO. 9: State the wholesale and retail price of Riomet®, and the sales and profits (sales less cost of goods sold) of Riomet®, for the past three years, and identify all documents consulted and relied on in providing this response.

OBJECTIONS: Plaintiffs object to this Request as overly broad, unduly burdensome, seeking information that is not relevant to any claim or defense in this litigation, and not proportionate to the needs of this case. Plaintiffs further object to this Request to the extent that it seeks information protected by attorney-client privilege, work-product immunity, joint defense privilege, common interest privilege, and/or any other applicable privilege, protection or immunity.

RESPONSE: Subject to and without waiver of the foregoing objections, to the extent that Plaintiffs assert commercial success as objective evidence of non-obviousness, Plaintiffs will produce documents and things concerning the sale price of Riomet® and representative sales figures and profits for Riomet® sold in the United States for the past three years from which information requested in this Interrogatory can be ascertained pursuant to Rule 33(d) of the Federal Rules of Civil Procedure, to the extent that they exist, are within the possession, custody, or control of Plaintiffs, and are located after a reasonable search, at an appropriate time pursuant to the

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Federal Rules of Civil Procedure, the Local Rules of Civil Practice, and by order of the Court.

Plaintiffs reserve the right to revise, clarify, and/or supplement this Interrogatory response in accordance with the Federal Rules of Civil Procedure.

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